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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,188	03/29/2001	John Greeven	10004662-1	1218

7590 09/27/2004

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EXAMINER	
SHAPIRO, JEFFERY A	

ART UNIT	PAPER NUMBER
3653	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/823,188	Applicant(s) GREEVEN ET AL.	
	Examiner Jeffrey A. Shapiro	Art Unit 3653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,23,30-32,36,48 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,23,30-32,36,48 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 22, 23, 30-32, 36, 48 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the phrase "unpackaged pharmaceutical", since applicant's pharmaceutical appears to be retained in a container from which it is dispensed.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 22-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liff (US 6,471,089 B2) in view of White (US 6,790,198 B1). Liff discloses the drug dispensing system as follows.

As described in Claims 22, 31, 32, 36, 53 and 54;

a. a controller (314);

b. a reservoir of pharmaceutical (20) ***specific to an individual and*** *to be dispensed over time to a patient, the pharmaceutical including at least*

one of tablets, liquids or gases, to be administered to a patient in individual or discrete doses according to a treatment regimen; (See col. 1, last line and col. 2, lines 1-7 for "dispensing a pharmaceutical over time" and col. 8, lines 16-20 for liquid and other forms of drugs being dispensed. See also col. 2, lines 52-54 which indicate that each bottle contains a certain number of doses, which can be construed as including one dose or a several doses. *Note that the reservoir can be construed as being specific to an individual, such as a doctor in a hospital or nurse, who can either administer/manage the dispensing or who might outright own the dispenser. Note also that an individual may be construed to be an institution such as a pharmacy, research center or a hospital.*)

c. a drug delivery mechanism ***located proximate to the patient at a location remote to a hospital*** (see figures 5-6c); (Note that the drug delivery mechanism may be construed to be located proximate to a patient **in** a hospital if that patient's room is located across from the dispenser for the entire hospital. Note also that locating such a dispenser **in** all hospital rooms could be construed to be no different than locating them across the hall or down the hall, at the other end of the floor. The limitations "proximate to the patient remote to a hospital" can be construed in a reasonably broad sense to even include locating a dispenser, such as Liff's element (20), at a bedside of a patient located **at their home**. If the home is located next door to the hospital, it can be construed as remote

from the hospital. Note further, that such limitations as "***located proximate to the patient at a location remote to a hospital***" are seen as arbitrary to the function of the system, and that for all practical purposes, Applicant's claimed system functions as Liff's system does.)

d. a data network interface coupled to said controller (see figure 13a);

As described in Claims 23, 24, 31-34, 37, 38 and 39;

e. sending messages to and from a health care service provider or drug supplier (see figure 14T, for example, noting payors, doctors, inventory and refills have files for information pertaining thereto),

f. said data message identifying the patient and the identity of the particular drug (see figure 14K, for example);

g. dispensing the pharmaceutical to the patient from the reservoir in a precise amount in response to signals from said controller; (Note that the dispenser dispenses drugs in a wide variety of forms, such as bottles or containers of pills, based upon signals from a controller, cited above.)

As described in Claims 25 and 55;

h. a human/display interface *including at least one of a tactile input device or a speech recognition device operatively coupled to the controller* (see figures 14A-14T, and 16, noting that laptop computers (566) and workstation (555) inherently have, at the very least, either a keyboard or a touchscreen—note also pen computers (558 and 568), which use a pen for input);

As described in Claims 26, 27, 35 and 58;

i. effecting payment for the provision of health care service or for a drug (see col. 18, lines 4-17);

As described in Claim 28;

j. the message is transported over the internet (see figure 18);

As described in Claim 29;

k. the message is transported via wireless (see col. 8, line 24;

As described in Claims 30 and 57;

l. a pharmaceutical level detector (182), see figure 7c;

m. the pharmaceutical level detector configured to ascertain at least one of measured weight of pharmaceutical remaining in the reservoir, decremented amount remaining in the reservoir, depth of measurement of pharmaceutical in the reservoir, and static pressure within the reservoir (note that the level detector (182) detects the level of the inventor remaining in a reservoir, noting that "the reservoir" can be reasonably broadly construed as being either a single dispensing device or several dispensing devices, and that such a level of inventory is construed as being a decremented amount, as the bottles of drugs are discrete items);

As described in Claim 48;

n. the pharmaceutical is at least one liquid material; (See col. 8, lines 16-20.)

As described in Claim 50;

o. the controller includes a memory device contained within the appliance (see Claim 30 of Liff et al, which states that a memory is connected to the system computer);

As described in Claim 51;

p. the memory device contains at least one treatment regimen regulating dispensing of individual doses of pharmaceutical to the patient; (see Claim 30 of Liff et al, which further states that the memory stores patient data and drug interaction data. See also col. 18, lines 42-65.)

Liff does not expressly disclose, but White discloses a reservoir (12) for releasing unpackaged doses (17) of pharmaceutical to a patient configured to contain a plurality of individual doses of unpackaged pharmaceutical by responding to signals from a controller (49) through a data network (55, 60), wherein the intelligent drug dispensing appliance (10) is sized and shaped for non-hospital placement proximate to the individual patient. See White, col. 10, lines 24-27, noting that the term bedside suggests that the dosage releasing device can be placed at any bedside, for example, in a home or a hospital.

Both Liff and White are analogous art because Liff discloses a hospital management system controlling drug dispensers for packaged doses of pharmaceutical and White discloses a hospital management system controlling a drug dispenser for unpackaged doses of pharmaceutical.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have used the dispenser of unpackaged doses of pharmaceutical in the hospital management system of Liff.

The suggestion/motivation for doing so would have been to more efficiently monitor and track unpackaged pharmaceutical doses dispensed by infusion pump devices. See White, col. 1, lines 14-20 and col. 2, lines 43-54. Note also Liff at col. 1, lines 43-49, which indicates that decentralized unit-based dispensing devices lowers costs relative to centrally located devices.

Therefore, it would have been obvious to combine White and Liff in order to obtain the invention as described in Claims 22, 31, 32, 36, 53 and 54.

5. Claims 53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shusterman (US 6,471,087 B1) in view of White. Shusterman discloses Applicant's claimed system as follows.

As described in Claim 53;

q. a controller (800) (See figure 8);

r. a reservoir of pharmaceutical specific to the individual patient to be dispensed over time (see col. 2, lines 23-36);

s. a drug dispensing mechanism (212), located proximate the patient at a location remote to a hospital, the drug delivery mechanism coupled to, and responsive to, the controller and to the reservoir to dispense the

pharmaceutical to the patient from the reservoir in a precise amount in response to signals from said controller (again, note col. 2, lines 25-27, which indicates that a precise dose of medication is stored in each compartment for dispensing);

t. a data network interface (400) coupled to said controller (see col. 4, lines 10-14);

As described in Claim 56;

u. at least one sensor (216, 218) operatively coupled to the controller, the sensor capable of providing data signals indicative of the patient's physical condition (see also figures 4b, 5, 6, 7);

Shusterman does not expressly disclose, but White discloses a reservoir (12) for releasing unpackaged doses (17) of pharmaceutical to a patient configured to contain a plurality of individual doses of unpackaged pharmaceutical by responding to signals from a controller (49) through a data network (55, 60), wherein the intelligent drug dispensing appliance (10) is sized and shaped for non-hospital placement proximate to the individual patient. See White, col. 10, lines 24-27, noting that the term bedside suggests that the dosage releasing device can be placed at any bedside, for example, in a home or a hospital.

Both Shusterman and White are analogous art because Shusterman discloses a central controller (100) system controlling drug dispensers (see Shusterman, figure 1 and col. 3, lines 65-67 and col. 4, lines 1-6) for packaged doses of pharmaceutical and

White discloses a hospital management system controlling a drug dispenser for unpackaged doses of pharmaceutical.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have used the dispenser of unpackaged doses of pharmaceutical in the system of Shusterman.

The suggestion/motivation for doing so would have been to more efficiently monitor and track unpackaged pharmaceutical doses dispensed by infusion pump devices. See White, col. 1, lines 14-20 and col. 2, lines 43-54. Note also Shusterman at col. 1, lines 19-38, which indicates that the medical profession endeavors to reducelabor costs associated with large nursing staffs monitoring patients by using accurate devices which remotely monitor drug dosage dispensing devices, thereby allowing fewer staff to safely monitor more patients located at remote areas such as their home.

Therefore, it would have been obvious to combine White and Shusterman in order to obtain the invention as described in Claims 53 and 56.

6. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liff et al in view of White and further in view of Monkhouse et al (US 6,514,518 B2). Liff et al discloses the drug dispensing system as described above. Liff et al does not expressly disclose, but Monkhouse discloses the following.

As described in Claim 49;

v. the drug delivery mechanism includes an ink-jet print head (22), (see col. 3, lines 6-57) capable of delivering precise amounts of the liquid (note that the "binder" is a liquid binder—see col. 5, lines 45-49);

At the time of the invention, it would have been obvious to one ordinarily skilled in the art to have coupled the ink jet printer drug dispensing device of Monkhouse et al to the networked system of Liff et al.

The suggestion/motivation would have been to provide drugs in a 3DP format, which provides a "multiphasic dosage form capable of providing delivery of multiple drugs having different release characteristics." See col. 2, lines 25-29 and col. 3, lines 5-17 of Monkhouse et al. See also Liff et al, abstract, noting that the system controls dispensing of drugs from dispensers and that it would be obvious to one of ordinary skill in the art to provide dispensers attached to Liff's system that would dispense drugs in a standard format adopted by the medical community. 3DP format dosages are just such a format.

Therefore, it would have been obvious to combine Liff et al, White and Monkhouse et al in order to obtain the invention as described in Claim 49.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liff et al in view of White and further in view of O"Brien (US 5,963,136). Liff et al discloses the drug dispensing system as described above. Liff et al does not expressly disclose, but O'Brien discloses the following.

As described in Claim 52;

w. wherein the data network interface (see figure 3, for example, noting that the system of O'Brien is a networked system—see also col. 8, lines 19-24) is adapted to be removably coupled to (note that it would have been expedient for one ordinarily skilled in the art to provide a coupling that is readily removable, such as a plug or computer cable with standard couplings, which are designed to be readily removable) and receive information derived from at least one patient monitoring sensor (see col. 5, lines 42-59, for example describing a temperature sensor), such information being an appliance diagnostic status (note col. 5, lines 56-59 describe monitoring an electro cardiogram, which can be construed as an appliance, the status of which would consist of the electronic output of the monitor, since the purpose of the EKG monitor is to provide diagnostic status of the patient, not necessarily the diagnostic status of the monitor itself);

At the time of the invention, it would have been obvious to one ordinarily skilled in the art to have coupled the networked prescription compliance system of O'Brien et al to the system of Liff et al.

The suggestion/motivation would have been to provide "interactive prescription compliance." See abstract of O'Brien et al. See also Liff et al, abstract, noting that the

system controls dispensing of drugs from dispensers in order to fill patient prescriptions and that it would be obvious to one of ordinary skill in the art to provide a prescription compliance capability to Liff's system, since patient compliance with a prescribed regimen of drugs is considered by the medical community to be a major goal in providing effective patient medical treatment.

Therefore, it would have been obvious to combine Liff et al, White and O'Brien in order to obtain the invention as described in Claim 49.

Response to Arguments

7. Applicant's arguments filed 9/24/03 have been fully considered but they are not persuasive. White discloses an unpackaged drug dosage dispensing apparatus, the drug dosage being assumed to be unpackaged in that the dose is in liquid form, being directly injected into the patient by a pump which is controlled to pump particular amounts of liquid medicine for particular time periods. This system, as described above, is interfaced with and controlled by a hospital information management system. As described above, it would have been obvious to one of ordinary skill in the art to have added the liquid dose dispensing device of White to the systems of either White or Shusterman so as to provide oversight and cost control for dispensing of liquid medicine. Therefore, as the claims read on the prior art, the rejection of Claims 22-39 and 48-58 is maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Shapiro whose telephone number is (703)308-3423. The examiner can normally be reached on Monday-Friday, 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald P. Walsh can be reached on (703)306-4173. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey A. Shapiro
Examiner
Art Unit 3653

September 21, 2004

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